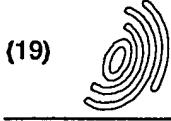


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ABSTRACT:

A lockable safety shield for a preffillable syringe is provided. The design of the lockable safety shield enhances pharmaceutical manufacturers' ease of assembling the various components as part of its filling or processing of the preffillable syringes in normal practice. A collar is attachable to the distal hub of the prefifiable syringe. A safety shield is axially slidable over the collar between a retracted position, wherein the distal end of the piercing element associated with the prefifiable syringe is exposed, and an extended position, wherein the safety shield is locked to the collar to protectively cover the distal end of the piercing element. The safety shield includes locking structure configured so that the shield, as supplied to the pharmaceutical manufacturer, can be easily fitted to the syringe. The locking structure includes at least one deflectable arm provided on the body of the shield. The deflectable arm includes a proximal end deflectable towards the interior of the shield. A stop member is provided on the interior of a shield in spaced relation to the proximal end of the deflectable arm. A ring is axially slidable over the shield to deflect the arm towards the interior of the shield to activate the locking structure. The safety shield is slid distally by an end user such that the collar is lockingly retained between the stop member and the proximal end of the deflectable arm. The collar, the stop member, and the deflectable arm may be configured to provide tactile as well as audible indication of locking to the end user.



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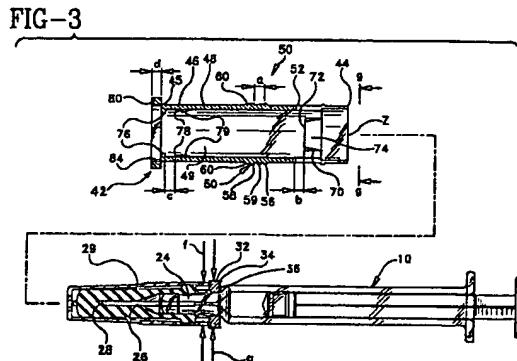
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(54) A lockable safety shield for a preffillable syringe

(57) A lockable safety shield (42) for a prefifiable syringe (10) is provided. The design of the lockable safety shield enhances pharmaceutical manufacturers' ease of assembling the various components as part of its filling or processing of the prefifiable syringes in normal practice. A collar (32) is attachable to the distal hub (24) of the prefifiable syringe. A safety shield (42) is axially slidable over the collar (32) between a retracted position, wherein the distal end (28) of the piercing element (26) associated with the prefifiable syringe (10) is exposed, and an extended position, wherein the safety shield (42) is locked to the collar (32) to protectively cover the distal end (28) of the piercing element (26). The safety shield (42) includes locking structure configured so that the shield, as supplied to the pharmaceutical manufacturer, can be easily fitted to the syringe (10). The locking structure includes at least one deflectable arm (50) provided on the body of the shield (42). The deflectable arm includes a proximal end (52) deflectable towards the interior of the shield. A stop member (70) is provided on the interior of a shield in spaced relation to the proximal end (52) of the deflectable arm (50). A ring (80) is axially slidable over the shield to deflect the arm (50) towards the interior of the shield (42) to activate the locking structure. The safety shield (42) is slid distally by an end user such that the collar (32) is lockingly retained between the stop member (70) and the proximal end (52) of the deflectable arm (50). The collar (32), the stop member (70) and the deflectable arm (50) may be configured to provide tactile as well as audible indication of locking to the end user.



Description**I. Field of the Invention.**

The invention relates to a lockable safety shield for a prefillable syringe, and more particularly, to a lockable safety shield for a prefillable syringe which is presented in a form enabling easy assembly by a pharmaceutical manufacturer and which can be subsequently activated by an end-user to form a locking mechanism for the shield.

II. Background.

As is known in the art, syringes are medical delivery devices utilizable to administer a medicament to a patient. Syringes are normally provided in prefillable form, wherein a set dosage of medicament can be filled into the syringe by a pharmaceutical manufacturer for distribution to the end user, or they are empty and intended to be filled by the end user from a vial or other source of medicament at the time administration of the medicament is desired.

Syringes typically include a barrel portion adapted to retain the medicament. The distal end of the barrel is normally configured to mate with a conventional piercing element, such as a pointed needle cannula made of steel or like material or a blunt ended cannula formed of plastic, to deliver the medicament contained in the barrel. A plunger rod is inserted through the open distal end of the syringe barrel and, through its engagement with an elastomeric or rubber-like stopper element fitted in a fluid-tight manner within the interior of the barrel, a user can apply manual force to the plunger to deliver the medicament through the piercing element.

More typically the case with pointed needle cannulae, accidental needle sticks that occur after the needle cannula has been used generally pose a greater health risk. To avoid such accidents, many prior art hypodermic syringes include a rigid cylindrical safety shield telescoped over the syringe barrel. The prior art safety shield can be slid from a proximal position where the needle cannula is exposed for use, to a distal position where the safety shield protectively surrounds the needle cannula.

Most prior art hypodermic syringes with cylindrical safety shields telescoped over the syringe barrel include structure for locking the safety shield in its distal position. Examples of such structures are found, for instance, in U.S. Patent Nos. 5,342,309 and 5,385,555 to Hausser and U.S. Patent No. 5,304,149 to Morigi. While generally suitable for the tasks employed, further improvements are still being sought. For instance, where the syringe is prefillable by a pharmaceutical manufacturer, it would be beneficial to incorporate improvements into the locking structure employed with the safety shields to better facilitate a pharmaceutical manufacturer's processing of the various components

associated with the syringe barrel and safety shield. These improvements should also facilitate the end user's normal use of the prefillable syringe and easy activation of the safety shield once safe disposal of the syringe is desired. The present invention represents such an improvement.

III. Summary of the Invention.

A lockable safety shield for prefillable syringes is provided. The lockable safety shield is designed to facilitate a pharmaceutical manufacturer's assembly of the various components associated with the lockable safety shield onto the syringe in conjunction with how the syringes are normally processed by the pharmaceutical manufacturer. The locking structure associated with the safety shield of the present invention may be designed such that it will not interfere with easy assembly by the pharmaceutical manufacturer, but which can be easily activated by an end user to facilitate safe covering of the distal end of a piercing element once the prefillable syringe has been used.

A collar is positionable about the distal end of the syringe barrel, and particularly configured for mating with the distal hub of a syringe barrel. The collar can be configured as a flat, disk-like structure, with a central opening through which the hub is fitted. Preferably, the collar is pre-affixed to the hub by the syringe manufacturer prior to delivery to the pharmaceutical manufacturer.

A safety shield is coaxially mounted over the syringe barrel and the collar, and is axially movable between a retracted position, wherein the distal tip of the piercing element is exposed, and an extended position, wherein the distal tip of the piercing element is covered. The safety shield includes a proximal end, a distal end, and a circumferential sidewall therebetween. The circumferential sidewall has an outside surface and an inside surface. Particularly, the shield is provided with user-activatable locking structure to secure the shield in its extended position respective of the syringe.

In one configuration, the locking structure includes at least one deflectable arm incorporated as part of the structure of the sidewall. The deflectable arm includes a distal end mounted with the circumferential sidewall, and a proximal end which is deflectable towards the interior of the shield. At least one stop member is mounted to the interior surface of the shield and spaced a distance from the proximal end of the deflectable arm to define a gap between the stop member and the proximal end of the deflectable arm. The deflectable arm has a free position, wherein the outside surface of the arm is substantially co-planar with the outside surface of the circumferential sidewall, and a locking position, wherein the deflectable arm is urged towards the interior of the shield so that the proximal end of the deflectable arm is positioned towards the interior of the shield.

Means are provided on the shield to activate the

locking structure. In one configuration, a circumferential ring is axially slidable about the outside surface of the shield between a first position, wherein the ring is spaced away from the deflectable arm, and a second position, wherein the ring is positioned against the at least one deflectable arm to secure the arm in the locking position. The ring may be secured to the distal end of the shield by a user-severable connection. The user-severable connection may entail, for instance, one or more frangible sections of material provided between the ring and the distal end of the shield. A pair of spaced abutments may be provided on the outside surface of the deflectable arm to retain the ring in its second position.

In practice, the collar is typically fitted to the hub of the prefabricated syringe by the syringe manufacturer and supplied to the pharmaceutical manufacturer in a sterile state, ready to be filled with a desired drug.

After the syringe has been filled with a drug and otherwise subjected to various processing operations, such as various particulate inspection operations, labeling operations, plunger rod assembly operations, or the like, the shield can be easily fitted to the syringe. The shield is slid proximally over the collar and syringe barrel to place same in a retracted position vis-a-vis the piercing element. Various structures associated with the shield, such as the stop member, may be provided with sloped surfaces to ensure smooth placement of the shield over the collar.

The locking structure is activated by detaching the ring from its user-severable connection, and sliding the ring proximally so that it is engaged between the abutments provided on the deflectable arm. The device may be shipped by a pharmaceutical manufacturer to an end user with the ring connected to the shield by its user-severable connection, so that the end-user himself activates the locking structure. Alternately and preferably, the pharmaceutical manufacturer activates the locking structure as part of the assembly process, such that the filled syringe is shipped to an end-user with the locking structure already activated.

After the syringe has been used to administer an injection, the shield is slid distally over the collar and the syringe barrel. The collar will be captured between the proximal end of the deflectable arm and the stop member in order to lock the shield in its extended position. In a preferred embodiment, the deflectable arm, the collar, and the stop members may be configured to provide audible as well as tactile indication to the end user that the shield has been securely locked with the collar.

In a preferred embodiment, at least two deflectable arms are provided. The two deflectable arms are located on diametrically opposite sides of the shield. Correspondingly, two stop members are provided to interact with the two deflectable arms. When viewed along the central axis of the shield, the stop members can be circumferentially aligned with a respective proximal end of the deflectable arms, or they can be circum-

ferentially offset from a respective proximal end.

IV. Brief Description of the Drawings

5 The invention will now be described in greater detail by way of reference to the appended drawings, wherein:

10 Figure 1 depicts, in perspective view, a lockable safety shield assembly of the present invention mounted to a syringe;
Figure 2 is an exploded perspective view of the lockable safety shield assembly of Figure 1;
Figure 3 is a cut-away view of the lockable safety shield of the present invention being mounted to a syringe barrel subsequent to its being filled by a pharmaceutical manufacturer;
Figure 4 is a cross-sectional view of the lockable safety shield of the present invention subsequent to mounting to a filled syringe;
Figure 5 is a cross-sectional view of the lockable safety shield of the present invention after an end user has activated the locking mechanism;
Figure 6 is a cross-sectional view of the lockable safety shield of the present invention after it has been urged in a distal direction by an end-user to protectively cover the needle cannula;
Figure 7 is partial cross-sectional view of the lockable safety shield of the present invention illustrating activation of the locking mechanism
Figure 8 is a partial cross-sectional view of the lockable safety shield of the present invention interacting with the collar at the distal end of the syringe barrel;
Figure 9 is an end elevational view of the lockable safety shield in accordance with the present invention; and
Figure 10 is a partial cross-sectional view of a preferred manner of configuring the collar in accordance with the present invention.

V. Detailed Description of the Invention

A convention utilized throughout this description is that the term "distal" refers to the direction furthest from 45 a practitioner, while the term "proximal" refers to the direction closest to a practitioner.

Turning now to the drawings, wherein like numerals denote like components, Figures 2-4 depict one embodiment of a lockable safety shield assembly 30 in accordance with the present invention. The lockable safety shield assembly 30 in accordance with the present invention can be provided in conjunction with a prefabricated syringe 10. As illustrated in Figs. 1 and 2, prefabricated syringe 10 includes a barrel 16 characterized by a proximal end 14, a distal end 12, and a hub 24 provided adjacent the distal end. A flange 18 may be provided about the proximal end, with a plunger rod 20 inserted through proximal end 14. Plunger rod 20 is attached to

a stopper 22 used for urging fluid through barrel 16. Fluid is emitted or aspirated via a fluid path, structured at distal end 12 of the syringe, that communicates with interior portions of barrel 16. For instance, if the pre-fillable syringe is configured as a luer lock syringe, the fluid path is configured as a luer tip (not shown) provided at distal end 12. Here, pre-fillable syringe 10 is illustrated with a fluid path configured as a piercing element 26, such as a pointed needle cannula. Piercing element 26 is characterized by a distal end 28.

The lockable safety shield assembly 30 in accordance with the present invention includes a collar 32 and a safety shield 42. Collar 32 can be formed as a disk-like structure characterized by an edge 34, a side portion 36, and a central opening 38 therebetween. Collar 32 has a thickness "e" and is characterized by a maximum diameter "g". Central opening 38 is fittable about hub 24 and may be retained thereto by friction fit, adhesives, mechanical means, or like structure, all known within the realm of the skilled artisan. If desired, edge 34 can display one or more raised nubs 39 having grooves 40. Grooves 40 can be aligned with complementary rails (not shown) provided on an interior portion of safety shield 42 for aligning the safety shield during the assembly process.

For purposes of clarity, Figures 1-6 depict collar 32 as having a rectangular cross-section, with side portion 36 displaying relatively flat walls that are directly linked to edge 34. If so desired, collar 32 can be configured in this manner to construct a lockable safety shield assembly in accordance with the present invention. However, Figure 10 depicts a preferred way for configuring the collar (here designated by the numeral 32a) so to provide better audible as well as tactile indication that shield 42 has been locked to the collar, as well as to enhance locking action between the shield and the collar, as will be further explained.

Referring then to Figure 10, as before, collar 32a includes an edge 34 and a side portion 36. However, here, side portion 36 is not completely flat. Rather, when viewed in cross-section, edge 34 and side portion 36 are linked by a locking tooth 34a. Locking tooth 34a features a distally-facing canted edge 36a and a proximally-facing canted edge 36b. Each of canted edges 36a, 36b of the locking tooth terminate at a shelf 37 that intersects with side portion 36. As before, if desired, grooves (not shown) can be provided on edge 34, for the purposes previously explained. As before, collar 32a includes a thickness "e" and a maximum diameter "g". Locking tooth 34a includes a maximum width "q" which need not be equal to thickness "e" displayed by collar 32a.

Safety shield 42 is characterized by a proximal end 44, a distal end 45, and a circumferential sidewall 46 therebetween. Circumferential sidewall 46 includes an outside surface 48 and an inside surface 49. Outside surface 48 is characterized by a diameter "N". Shield 42 is slidable both over collar 32, mounted to hub 24, and

over syringe barrel 16 between a retracted position (Figs. 1, 4 and 5), wherein distal tip 28 of piercing element 26 is exposed, and an extended position (Fig. 6), wherein the distal tip of the piercing element is protectively covered.

Lockable safety shield assembly 30 in accordance with the present invention includes user-activatable locking structure. A feature of the lockable safety shield assembly in accordance with the present invention is that the locking structure can be implemented such that it is not "activated" during assembly of the components, making it easier to assemble the components to syringe 10. Subsequent to assembly of the components, the locking structure can be "activated", putting the safety shield assembly in a ready-to-use state.

Making reference to Figs. 1-3 and 7-9, shield 42 features at least one deflectable arm 50. Arm 50 is preferably provided as part of the structure of the shield. Arm 50, which may be molded as part of the shield or thereafter created from the shield via various cutting processes, includes a distal end 54 and a proximal end 52. Distal end 54 is resiliently affixed to sidewall 46 such as by a living hinge arrangement, while proximal end 52 is not attached to the sidewall and is configured for free movement towards an interior portion of shield 42. In a preferred embodiment, at least two deflectable arms 50 are provided on shield 42, with these two arms 50 located on diametrically-opposite sides of shield 42. Arms 50 are thus configured for a free position (Figures 1 and 4), wherein the surface of the arms are substantially co-planar with circumferential sidewall 46 of the shield, and a locking position (Figures 5, 7, and 8), wherein proximal ends 52 of arms 50 are urged towards the interior of the shield.

As best reflected by Figures 7 and 8, in a preferred configuration, proximal ends 52 of the deflectable arms are not straight. Rather, to best make use of the features of collar 32a (Figure 10), proximal ends 52 are preferably canted in a manner such that when the deflectable arms are positioned towards the interior of the shield, the proximal ends will be oriented to lockingly cooperate with distally-facing canted edge 36a of collar 32a, as will be explained hereinbelow.

At least one stop member 70 is provided on inside surface 49 of the shield in an area adjacent proximal end 44. In a preferred embodiment, two stop members 70 are provided, each corresponding to a respective one of two deflectable arms 50 (see Fig. 9). Stop member 70 includes a distally-facing stop surface 72. Stop surface 72 is preferably spaced from proximal end 52 of the deflectable arm a distance "b" as measured along central axis "z" of the shield (see Fig. 3).

As best illustrated in Figures 7 and 8, in a preferred configuration, stop surface 72 is preferably not straight. Rather, to best make use of the features of collar 32a (Figure 10), stop surface 72 is preferably canted in a manner such that it will lockingly cooperate with proximally-facing canted edge 36b of collar 32a, as will be

explained hereinbelow.

Stop member 70 also includes a proximally-facing sloped surface 74. Proximally-facing sloped surface 74 facilitates sliding of shield 42 over collar 32 when the shield is placed in its retracted position. Stop member 70 can be located such that stop surfaces 72 are circumferentially aligned with respective proximal ends 52 of deflectable arms 50, when viewed along central axis "Z" of the shield. Alternately, if desired, stop members 70 can be placed on interior surface 49 of the shield such that they are circumferentially offset from respective proximal ends 52 of the deflectable arms, when viewed along central axis "Z" of the shield.

Shield 42 includes structure permitting activation of the deflectable arms 50 into their locked position (Figs. 5, 6, 7, 8). A respective pair of distal and proximal abutments 58, 56 are provided on deflectable arms 50. Distal abutment 58, which includes a distally-facing sloped surface 60, is spaced from proximal abutment 56 by a distance "a" that defines a gap 59. As seen in Figs. 3 and 4, in a preferred embodiment where two diametrically opposite deflectable arms are included, the diametrically opposite pair of gaps 59 define a diameter "M" slightly greater than diameter "N" defined by outside surface 48 of the shield when the arms 50 are in their free position. The effect is that gap 59 is configured so that it is elevated from the level of surrounding outside surface 48 of cylindrical sidewall 46 prior to activation of deflectable arm 50.

A circumferential ring 80 having an inside wall 82 is disposed for coaxial movement with circumferential sidewall 46 of the shield. Inside wall 82 has a diameter "P" at least equal to, if not slightly less than, diameter "N" defined by the outside surface of shield 42. Ring 80 has a width "d" at least equal to, if not slightly less than, the width of gap 59 as defined by distance "a". To simplify later assembly operations by the pharmaceutical manufacturer, shield 42 is typically supplied by the component manufacturer such that ring 80 is configured together with the shield, with the ring retained to shield 42, for instance, by a user-severable connection. That is to say, shield 42 and ring 80 are preferably supplied to the pharmaceutical manufacturer as a single unit. For example, ring 80 can be supplied by the component manufacturer such that it is secured to the shield by a user-severable connection such as a threaded connection. Preferably, and as is disclosed herein, ring 82 is secured to distal end 45 of the shield by one or more user-severable connections 84 configured as thinned, frangible sections of material between ring 80 and proximal end 45 of the shield. This type of structure also permits the component manufacturer to easily form ring 80 and shield 42 as a single molding.

Shield 42 further includes structure for retaining shield 42 in the retracted position without being inadvertently "over-retracted" with respect to syringe 10 and, hence, inadvertently removed from syringe 10 in the proximal direction. As seen in Fig. 3, one or more

distal stop members 76 can be provided on interior surface 49 of the shield adjacent distal end 45. Distal stop members 76 are configured to engage a distally-facing side portion 36 of the collar to prevent shield 42 from being over-retracted in a proximal direction. If desired, one or more tertiary stop members 78 can be provided on shield 42, each spaced from a respective distal stop member 76 by a distance "c" approximately equal to thickness "e" of collar 32. Hence, collar 32 can be releasably retained between distal stop members 76 and tertiary stop members 78 when the shield is in its retracted position. If desired, tertiary stop member 78 can be provided with a proximally-facing sloped surface 79 which, like proximally-facing slope surface 74 associated with stop members 70, assists in the assembly of shield 42 about collar 32.

Operation of a device will now be explained.

Preliminarily, as has been explained, collar 32 is typically pre-fitted about hub 24 by the syringe manufacturer. As also seen in Figure 3, means can be fitted to the syringe adjacent the distal end to provide a barrier to the fluid path leading to the medicament which will be contained within barrel 16. The barrier is normally fitted by the syringe manufacturer and here, can be fitted to the syringe barrel in a process subsequent to placement of collar 32. If the fluid path is structured as a luer tip, for instance, a luer tip cap can be fitted. Here, where a piercing element 26 is configured on the syringe, a well-known needle shield 29 can be fitted about piercing element 26 so that a proximal-end of needle shield 29 rests against collar 32. Collar 32 should be configured such that maximum diameter "g" is at least slightly greater than a maximum diameter "f" displayed by needle shield 29, such that needle shield 29 will not interfere between operation of collar 32 and shield 42.

Syringe 10 is thus supplied to the pharmaceutical manufacturer in a sterile state, ready to be filled with a desired drug and otherwise processed in a well-known manner. For instance, various filling operations, particular inspection operations, labelling operations, plunger rod assembly operations may be conducted on the syringe.

After the various filling and processing operations have been conducted, shield 42 may thereafter be fitted to the syringe by the pharmaceutical manufacturer. Proximally-facing sloped surfaces 74 and, if provided, 79, assist shield 42 to smoothly surpass edge 34 of the collar. Shield 42 is slid over syringe barrel 16 in a proximal direction, such that collar 32 rests against distal stop members 76. If tertiary stop members 78 are provided, collar 32 will be releasably retained between distal stop members 76 and tertiary members 78, with needle shield 29 affixed to piercing element 26. Syringe 10, together with lockable safety shield assembly 30, can be shipped by the pharmaceutical manufacturer to an end-user in a ready-to-use state.

Fig. 4 is representative of safety shield 42 of the present invention mounted about syringe 10 prior to

activation of locking structure, while Fig. 5 is representative of the same construction after activation of the locking structure. Preferably, a pharmaceutical manufacturer will ship the preffillable syringe to the end-user in the state shown in Fig. 5, such that the locking structure is pre-activated by the pharmaceutical manufacturer, rather than by the end-user himself. If the locking structure is activated by a pharmaceutical manufacturer rather than by the end-user, it will be realized by the skilled artisan that the step of sliding ring 80 towards gap 59 can be effected as a final step in an assembly motion during which shield 42 is fitted to the preffillable syringe. In this vein, it will also be realized that because the component manufacturer preferably supplies the ring and shield to pharmaceutical manufacturer as a single unit, assembly operations are simplified, in that the pharmaceutical manufacturer need only be concerned with sorting, orienting, distributing and then assembling a single unit about the syringe, rather than doing the same to a ring and shield separately supplied.

Nonetheless, Fig. 5 illustrates activation of the locking structure, whether by the pharmaceutical manufacturer or by an end-user. The user-severable connections 84 connecting ring 80 to distal end 45 of the shield have been severed, and ring 80 has been slid proximally with respect to shield 42. Aided by distally-facing sloped surface 60 associated with distal abutment 58, inside surface 82 of the ring glides along outside surface 48 of the shield, over distally-facing sloped surface 60, and is secured in gap 59 defined between distal abutment 58 and proximal abutment 56. Because inside diameter "P" of ring 80 is greater than diameter "M" between diametrically-opposed gaps 59, ring 80 exerts an inwardly-directed force upon deflectable arms 50. Deflectable arms 50 are thus deflected about their distal ends 54, such that proximal ends 52 are pushed towards the interior of shield 42. As a deflectable arm 50 is urged inwardly (see particularly Figs. 7 and 8), proximal end 52 of a given deflectable arm and stop surface 72 of a respective stop element 70 define a gap 100 between them. Gap 100 is designed to "capture" collar 32 when the shield is slid distally to cover piercing element 26. Where the collar has a flat side portion 36, then gap 100 should have a width "b" at least equal, if not slightly greater than, thickness "e" of the collar to securely retain collar 32 in gap 100. If, as depicted in Figure 10, the collar is configured with locking tooth 34a, then width "b" should be chosen so as to accommodate the maximum width "q" associated with locking tooth 34a, so that locking tooth 34a is securely retained in gap 100.

Fig. 6 is representative of shield 42 in its extended position to protectively cover distal tip 28 of the piercing element. After needle shield 29 has been removed and an injection administered in the usual manner, shield 42 is grasped by an end-user and slid distally with respect to syringe 10. Collar 32, which is fixed to hub 24, will thus be urged towards proximal end 44 of the shield.

Owing to the resiliency of deflectable arms 50, edge 34 of the collar will push arms 50 in an outward direction from the interior of the shield and thus will pass along the length of arms 50. Edge 34 will eventually deflect past proximal end 52, causing the arm to re-deflect in an inward direction toward the interior of the shield. Thus, collar 32 will come to rest in gap 100, with the collar sandwiched between proximal end 52 and stop surface 72. Collar 32 is thus lockingly held between stop surface 72 and proximal end 52 of the arm, arresting further movement of the shield in either proximal or distal directions respective of syringe 10. Accordingly, shield 42 is retained in its extended position with respect to piercing element 26, protectively covering distal tip 28 against inadvertent touch contact.

As previously explained, in a preferred configuration (Figures 7, 8 and 10), deflectable arms 50, stop members 70 and collar 32a are configured to provide good audible as well as tactile indication that shield 42 has been locked to collar 32a. As edge 34 of collar 32a clears proximal end 52 of the deflectable arm, locking tooth 34a enters gap 100. As soon as the locking tooth enters gap 100, the resilient characteristics of the deflectable arm cause the arm to re-deflect in an inward direction toward the interior of the shield. At this moment, an interior portion 49a of deflectable arm 50 that is located adjacent proximal end 52 is thrust against shelf 37 of collar 32a. As soon as interior portion 49a is thrust against shelf 37, tactile as well as audible sensations are transmitted to the user, signaling that shield 42 has been locked to collar 32a. Owing to the canted orientations of both proximal end 52 of the deflectable arms and stop surface 72 of the stop members 70, each of the proximal ends 52 and stop surfaces 72 are lockingly retained against their respective distally facing canted edge 36a and proximally-facing canted edge 36b, such that tooth 34a is securely locked within gap 100. Thus, by a simple distal movement, shield 42 is self-locking with collar 34a.

The various components can be formed from suitable materials, such as medical-grade plastics or the like. They may be injection molded in manners well-known to the skilled artisan, resulting in reliable and cost-effective production of the locking shield assembly. The locking shield assembly of the present invention can be adapted with preffillable syringes of various dimensions and capacities. Various enhancements can be provided to permit easy assembly. For instance, sections of the sidewall adjacent the proximal end of the shield can be thinned, or slits can be incorporated in an area of the shield between the proximal end of the shield and the proximal edge of the deflectable arms, all to enhance the easier sliding of the shield proximally over the collar. Of course, the dimensions for the various components can be selected such that when the shield is in its retracted position, the distal tip of the piercing element is exposable for an injection, and when the shield in its extended position, the distal tip of the piercing element

will be protectively covered to enable the end user to safely discard the syringe.

It will be appreciated and understood by those skilled in the art that further and additional revisions to the invention may be devised without departing from the spirit and scope of the appended claims, the invention not being limited to the specific embodiments shown.

Claims

1. A medical device, comprising:

a barrel having a proximal and distal ends; a piercing element extending from the distal end of the barrel and having a distal tip; a collar positioned at the distal end of the barrel, the collar having an edge; and a shield mounted about said barrel and axially movable between a retracted position, wherein the distal tip of the piercing element is exposed, and an extended position, wherein the distal tip of the piercing element is covered, the shield having a proximal end, a distal end, and a circumferential sidewall therebetween, the circumferential sidewall having an outside surface and an inside surface;

user-activatable locking means to secure the shield in the extended position, the user activatable locking means comprising

at least one deflectable arm having a distal end mounted with the circumferential sidewall and a proximal end deflectable towards the interior of the shield, said at least one arm having a free position wherein the arm is substantially coplanar with the circumferential sidewall of the shield, and a locking position, wherein the arm is deflected towards the interior of said shield so that the proximal end is positioned towards the interior of the shield, at least one stop member mounted to the interior surface of the shield adjacent the proximal end of the shield to define a gap between the stop member and the proximal end of the deflectable arm, and a ring axially slidable around the outside surface of the shield between a first position wherein the ring is spaced away from the at least one deflectable arm and a second position wherein the ring is positioned against said at least one deflectable arm to secure the arm in the locking position.

2. The medical device of claim 1, wherein said ring is secured to the distal end of the shield by a user-severable connection in the first position, wherein an end user may sever the user-severable connec-

tion to axially slide the ring to the second position.

- 3. The medical device of claim 1, wherein the stop member includes a proximally-facing sloped surface and a distally facing stop surface, the gap defined between said stop surface and the proximal end of said at least one deflectable arm.**
- 4. The medical device of claim 1, wherein said deflectable arm comprises structure for retaining the ring in the second position.**
- 5. The medical device of claim 4, wherein the structure for retaining comprises a distal abutment and a proximal abutment spaced from said distal abutment, wherein said ring is retained in the space between said proximal and distal abutments.**
- 6. The medical device of claim 5, wherein the space between said proximal and distal abutments is raised from the surface of said at least one deflectable arm, wherein said space is substantially co-planar with the circumferential sidewall of the shield when said deflectable arm is in the locking position.**
- 7. The medical device of claim 5, wherein said distal abutment includes a distally-facing sloped surface, wherein said ring is urged over the distally-facing sloped surface of the distal abutment into said second position.**
- 8. The medical device of claim 1, wherein said shield further comprises a second stop located on the interior surface of the shield adjacent the distal end, said second stop engageable with the collar when said shield is in the retracted position.**
- 9. The medical device of claim 8, further comprising a third stop located on the interior surface of the shield proximally of the second stop, wherein the edge of the collar is retained between the second and third stops when said shield is in the retracted position.**
- 10. The medical device of claim 1, wherein a locking tooth is provided on the edge of the collar.**
- 11. The medical device of claim 10, wherein the proximal end of the at least one deflectable arm is oriented for locking engagement with the locking tooth of the collar.**

12. A medical device, comprising:

a barrel having a proximal and distal ends; a piercing element extending from the distal end of the barrel and having a distal tip; a collar positioned at the distal end of the bar-

rel, the collar having a side portion and a circumferential edge; and a shield mounted about said barrel and axially movable between a retracted position, wherein the distal tip of the piercing element is exposed, and an extended position, wherein the distal tip of the piercing element is covered, said shield having a proximal end, a distal end, and a circumferential sidewall therebetween, the circumferential sidewall having an outside surface and an inside surface, the shield including user activatable locking means to secure the shield in the extended position, the user activatable locking means comprising

at least one deflectable arm having a distal end mounted with the circumferential sidewall, a proximal end deflectable towards the interior of the shield, and an outside surface therebetween, the proximal end of the deflectable arm defining an edge for engaging said collar, said at least one arm having a free position wherein the outside surface of said arm is substantially coplanar with the circumferential wall of the shield, and a locking position, wherein said arm is deflected towards the interior of said shield so that said edge is positioned towards the interior of the shield, said deflectable arm including a pair of abutments on the outside surface spaced apart from one another,

at least one stop member mounted to the interior surface of the shield adjacent the proximal end of the shield to define a gap between the stop member and the proximal end of the deflectable arm, and a ring retained to the shield by a user-severable connection, said ring axially slidable around the outside surface of the shield between a first position wherein the ring is spaced away from the at least one deflectable arm and a second position wherein the ring is positioned between the pair of abutments on said at least one deflectable arm to secure the arm in the locking position,

wherein the ring is slid proximally along the shield until the ring is positioned between the pair of abutments, and the shield thereafter urged distally so that the circumferential edge of the collar enters into the gap defined between the stop member and the proximal end of the arm so that the edge of the arm engages the collar.

13. The medical device of claim 12, further comprising

at least one slit in said circumferential sidewall intermediate the proximal end of the shield the proximal edge of the deflectable arm.

- 5 14. The medical device of claim 12, wherein the user-severable connection comprises one or more thinned sections of material between said ring and the distal end of the shield.
- 10 15. The medical device of claim 2, wherein the user-severable connection comprises one or more thinned sections of material between said ring and the distal end of the shield.
- 15 16. A medical device, comprising:
 - a barrel having a proximal and distal ends;
 - a piercing element extending from the distal end of the barrel and having a distal tip;
 - a collar positioned at the distal end of the barrel, the collar having an edge and a locking tooth defined at the edge; and
 - a shield mounted about said barrel and axially movable between a retracted position, wherein the distal tip of the piercing element is exposed, and an extended position, wherein the distal tip of the piercing element is covered, the shield having a proximal end, a distal end, and a circumferential sidewall therebetween, the circumferential sidewall having an outside surface and an inside surface;
 - user-activatable locking means to secure the shield in the extended position, the user activatable locking means comprising
 - 20 at least one deflectable arm having a distal end mounted with the circumferential sidewall and a canted proximal end deflectable towards the interior of the shield for locking engagement with the locking tooth of the collar, the at least one arm having a free position wherein the arm is substantially coplanar with the circumferential sidewall of the shield, and a locking position, wherein the arm is deflected towards the interior of said shield so that the proximal end is positioned towards the interior of the shield,
 - 25 at least one stop member mounted to the interior surface of the shield adjacent the proximal end of the shield and having a canted stop surface, the stop member placed on the shield to define a gap between the canted stop surface and the canted proximal end of the deflectable arm, and
 - 30 a ring axially slidable around the outside surface of the shield between a first posi-
- 35 at least one deflectable arm having a distal end mounted with the circumferential sidewall and a canted proximal end deflectable towards the interior of the shield for locking engagement with the locking tooth of the collar, the at least one arm having a free position wherein the arm is substantially coplanar with the circumferential sidewall of the shield, and a locking position, wherein the arm is deflected towards the interior of said shield so that the proximal end is positioned towards the interior of the shield,
- 40 at least one stop member mounted to the interior surface of the shield adjacent the proximal end of the shield and having a canted stop surface, the stop member placed on the shield to define a gap between the canted stop surface and the canted proximal end of the deflectable arm, and
- 45 a ring axially slidable around the outside surface of the shield between a first posi-
- 50 at least one deflectable arm having a distal end mounted with the circumferential sidewall and a canted proximal end deflectable towards the interior of the shield for locking engagement with the locking tooth of the collar, the at least one arm having a free position wherein the arm is substantially coplanar with the circumferential sidewall of the shield, and a locking position, wherein the arm is deflected towards the interior of said shield so that the proximal end is positioned towards the interior of the shield,
- 55 at least one stop member mounted to the interior surface of the shield adjacent the proximal end of the shield and having a canted stop surface, the stop member placed on the shield to define a gap between the canted stop surface and the canted proximal end of the deflectable arm, and

tion wherein the ring is spaced away from
the at least one deflectable arm and a sec-
ond position wherein the ring is positioned
against said at least one deflectable arm to
secure the arm in the locking position,

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wherein after the ring has been
placed in the second position, the shield is
urged distally so that the locking tooth
enters into the gap between the canted
stop surface and the canted proximal end
of the arm to lock the tooth in the gap.

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17. The medical device of claim 16, wherein an audible
indication is produced as the locking tooth enters
the gap.

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18. The medical device of claim 16, wherein a tactile
indication is produced as the locking tooth enters
the gap.

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FIG-1

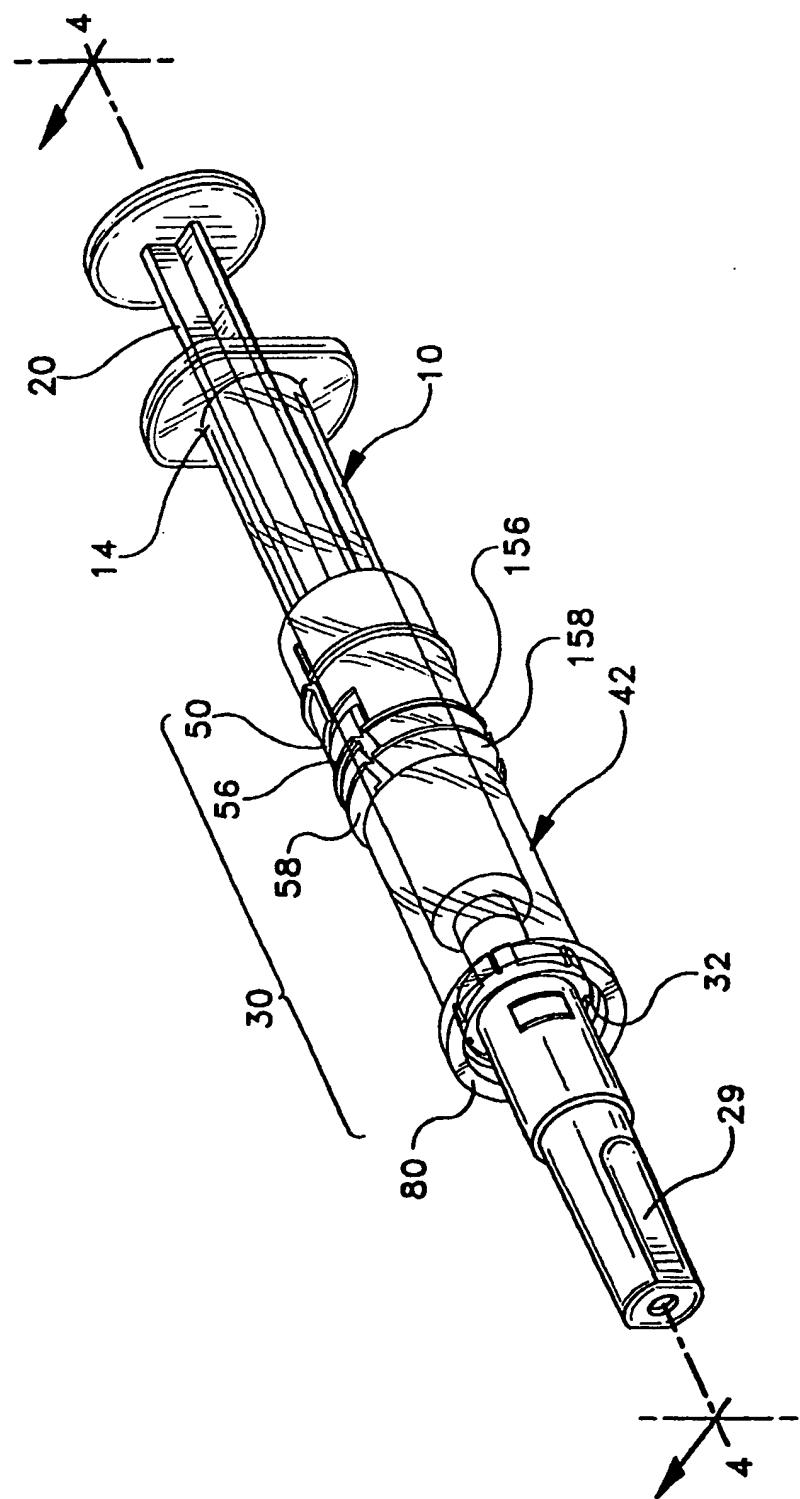


FIG-2

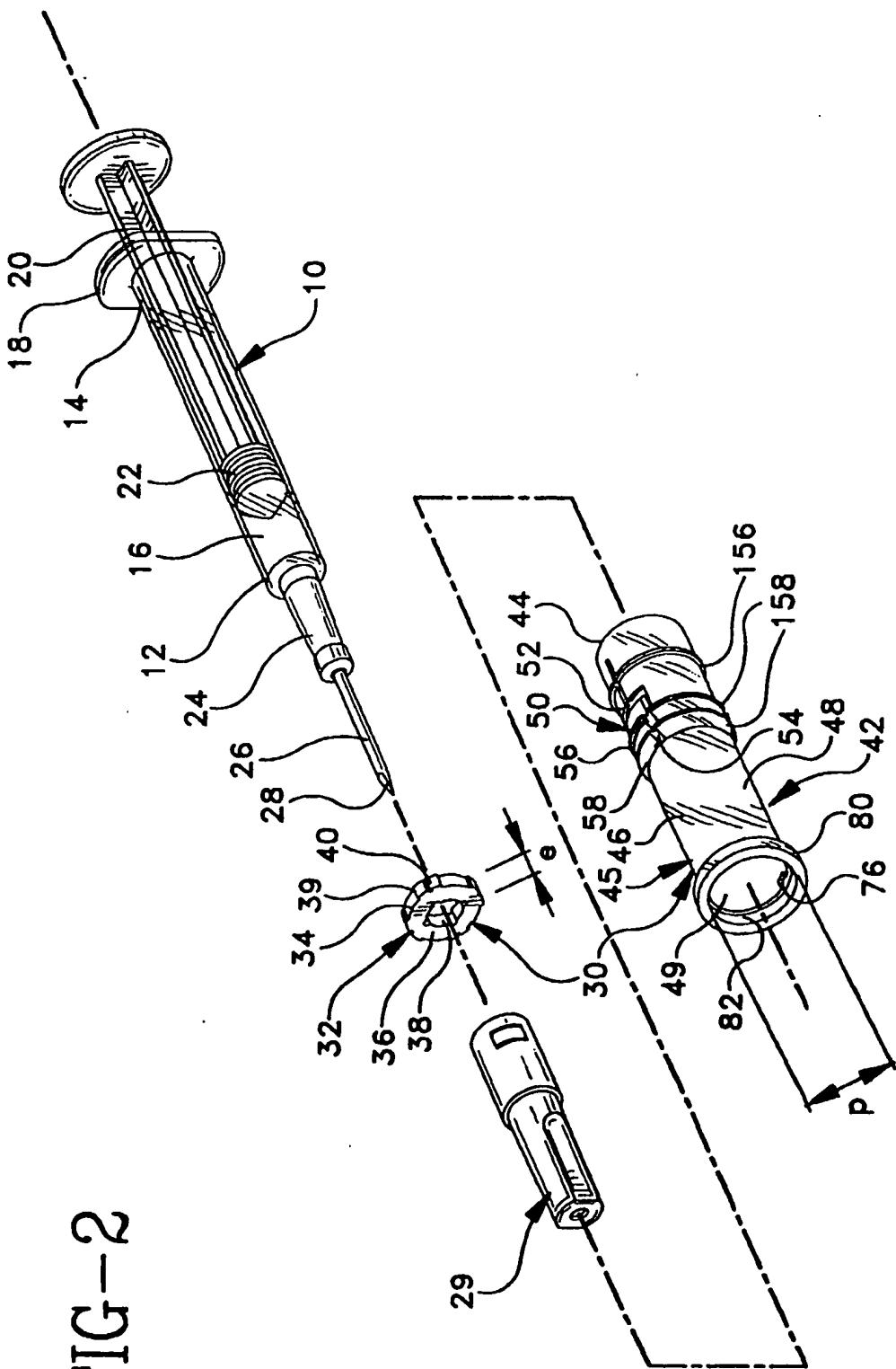


FIG-3

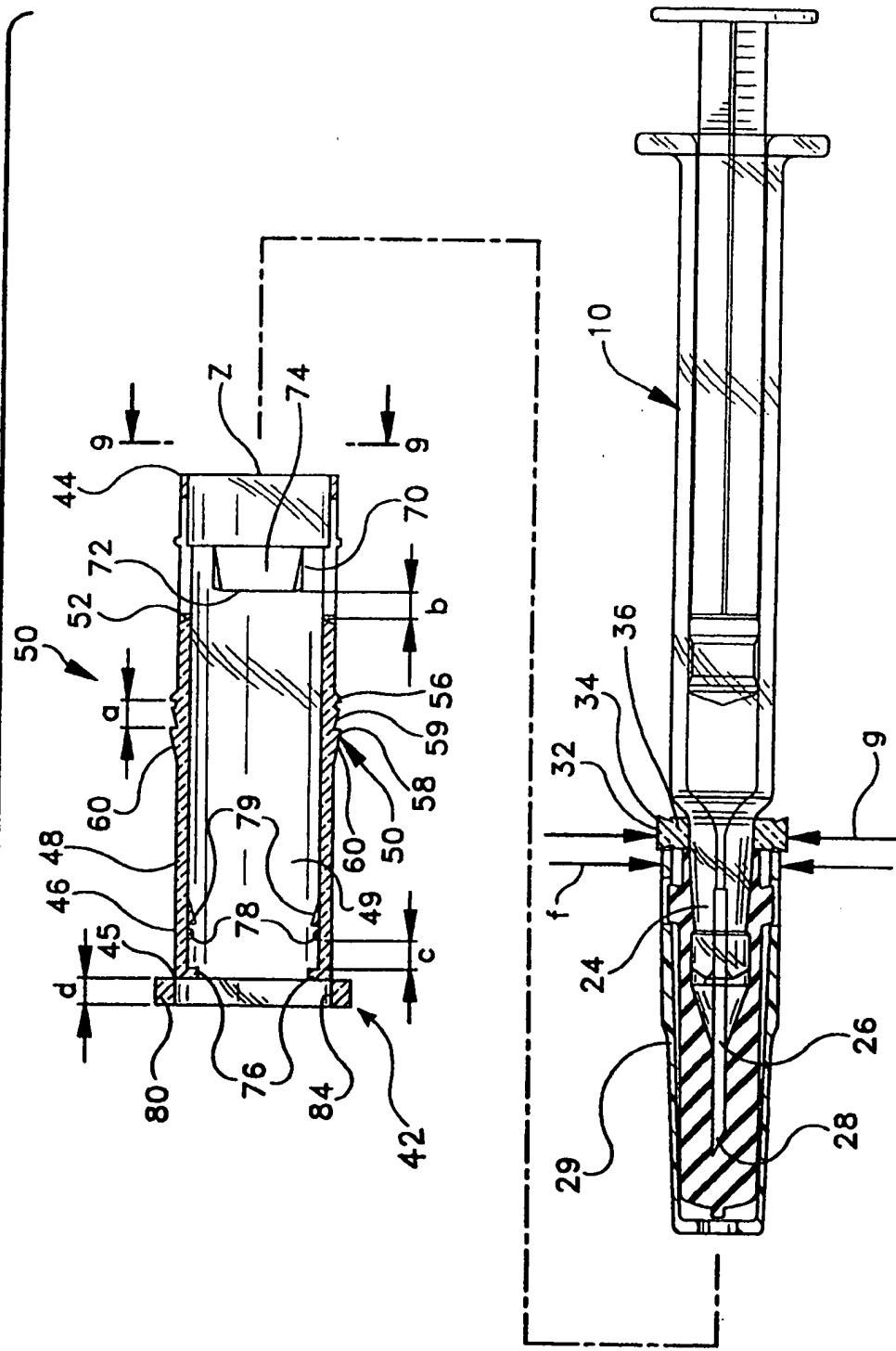


FIG-4

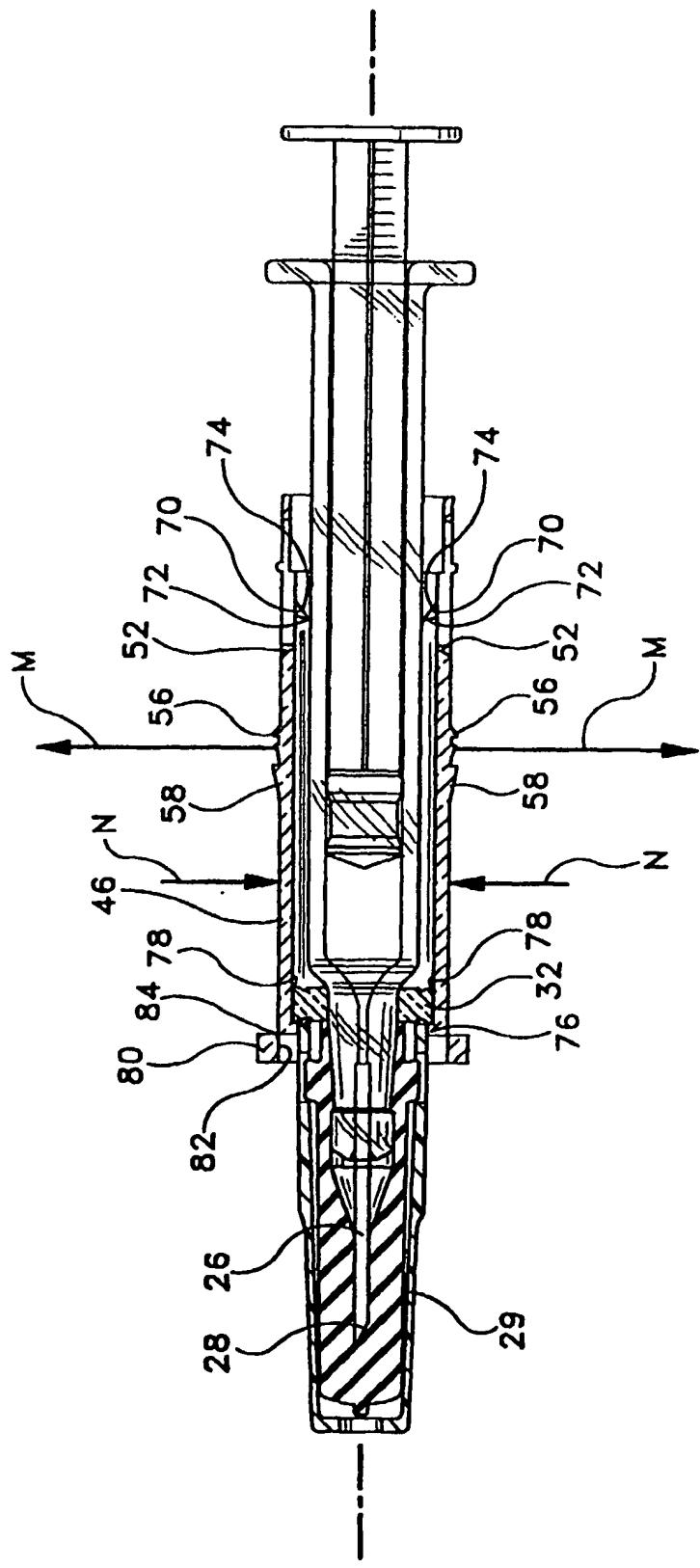


FIG-5

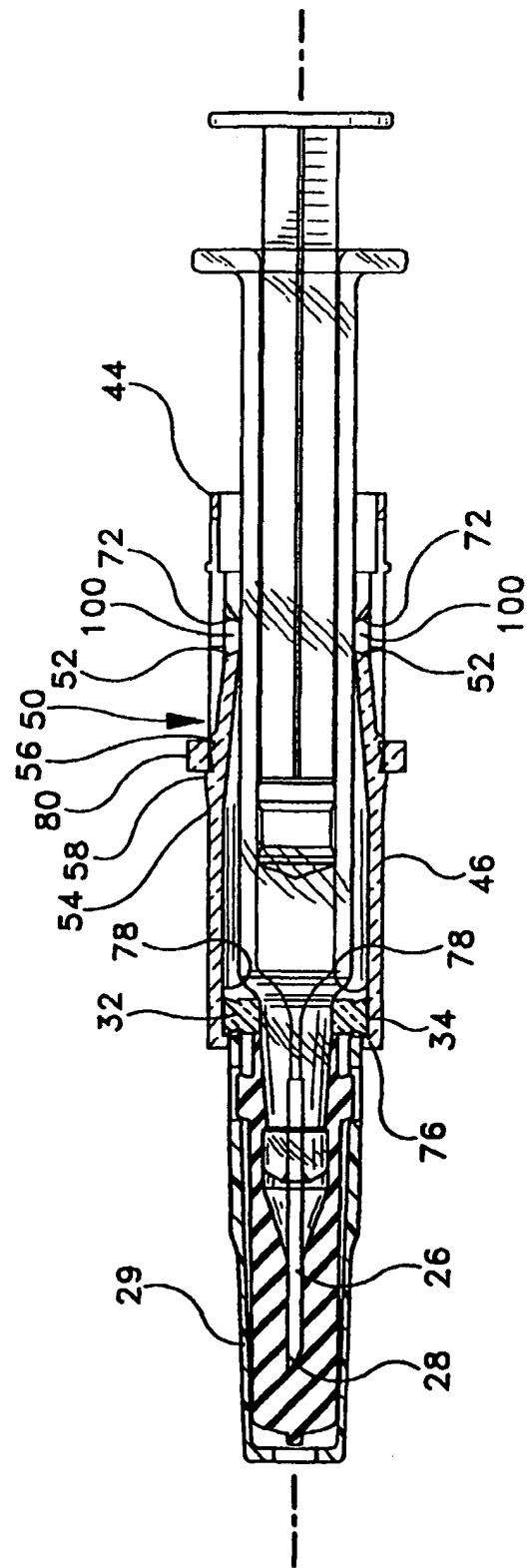


FIG-6

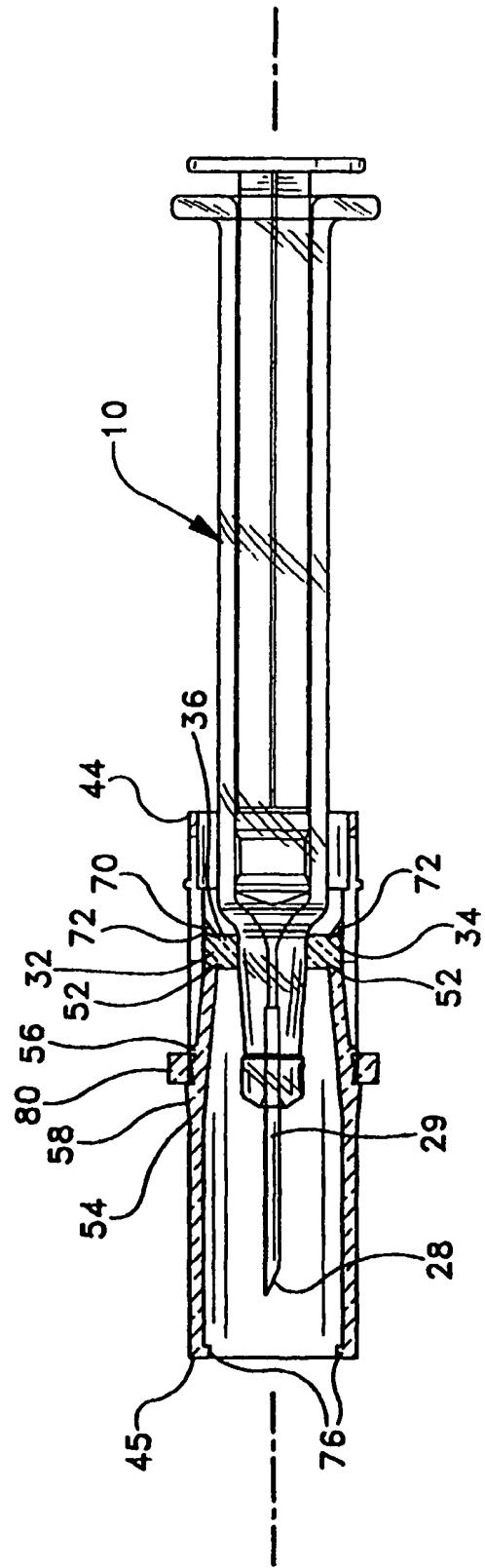


FIG-8

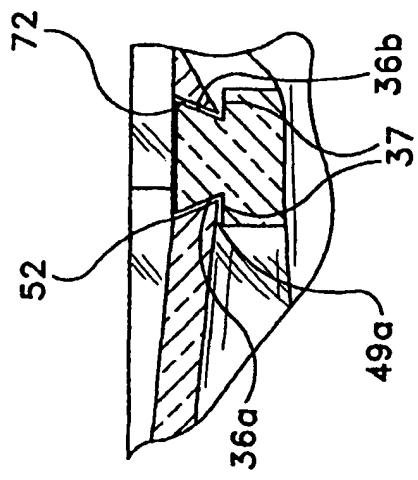


FIG-7

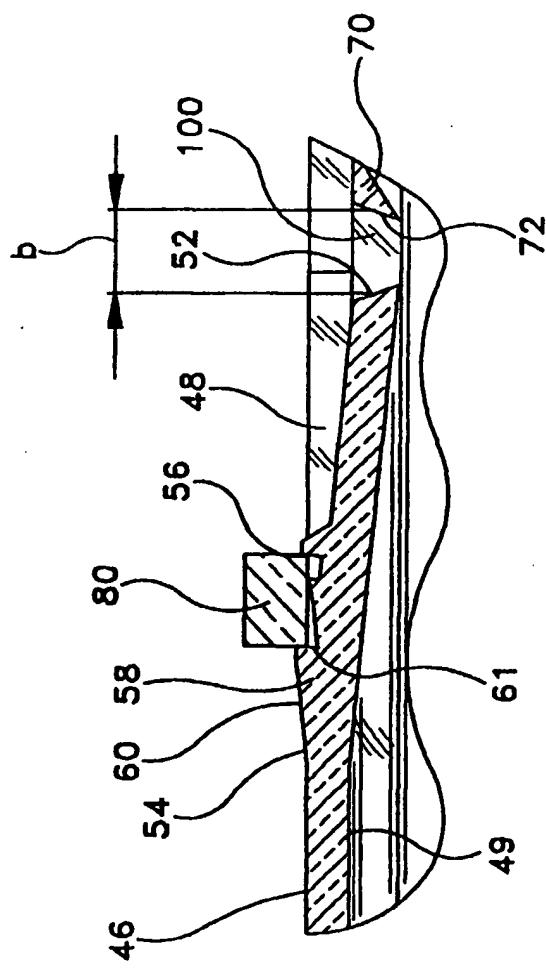


FIG-10

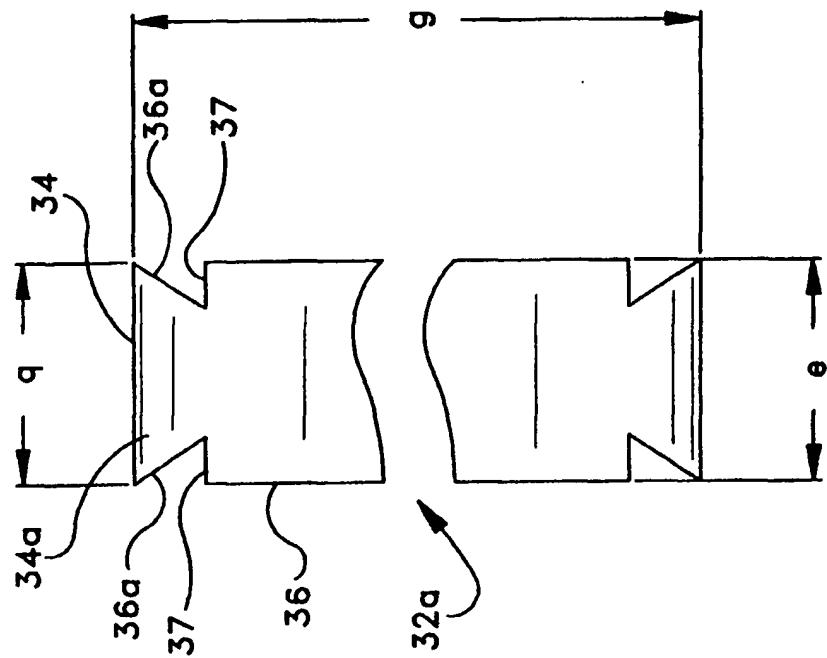


FIG-9

